

K092409 HYDRO-GUARD MINI BREATHING FILTER AND HEAT AND MOISTURE EXCHANGER AND AIR-GUARD CLEAR BREATHING FILTERMar 10, 2010
216 days to decisionK092409 · Product code: **CAH** · General Hospital
Source: <https://www.510kdatabase.net/k092409/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Filter, Bacterial, Breathing-circuit (CAH) |
| Date received | Aug 6, 2009 |
| Decision date | Mar 10, 2010 |
| Days to decision | 216 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---|
| Company | Intersurgical, Inc. |
| Location | Cazenovia, NY, US |
| Contact | MICHAEL ZALEWSKI |
| 510(k) history | 18 submissions · 18 cleared · 1991-2013 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k092409/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 24, 2026